

K070971

MAY 23 2007

510(k) Summary

Submitter's Name/Address

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Date of Preparation of this Summary:

March 30, 2007

Device Trade or Proprietary Name:

Sentinel Clin Chem Cal

**Device Common/Usual Name or
Classification Name:**

CLIN CHEM CAL

Classification Number/Class:

JIX/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Device Description:

Original (Clin Chem Cal K051452).

1. The Sentinel Clin Chem Cal is a lyophilized Calibrator prepared with human based serum. It consists of 4 x 3 mL bottles of lyophilized material containing pancreatic amylase, cholinesterase in a lyophilised human serum matrix. This material is stable until the date printed on the label when stored as directed. Calibrator traceability was stated as certified to Deutsche Gesellschaft für Klinische Chemie (DGKC) for Cholinesterase
2. International Federation of Clinical Chemistry (IFCC) for Pancreatic Amylase

Modified Clin Chem Cal

The Sentinel Clin Chem Cal is a lyophilized Calibrator prepared with human based serum. It consists of 4 x 3 mL bottles of lyophilized material containing pancreatic amylase, ~~cholinesterase~~ Creatinine, Lithium, Alpha-Hydroxybutyrate Dehydrogenase and ~~“Cholinesterase Dibucaine-Inhibited”~~ in a lyophilized human serum matrix. This material is stable until the date printed on the label when stored as directed. Calibrator traceability was stated as certified to

1. Deutsche Gesellschaft für Klinische Chemie (DGKC) for Cholinesterase, Cholinesterase Dibucaine-Inhibited and for Alpha-hydroxybutyrate Dehydrogenase
2. International Federation of Clinical Chemistry (IFCC) for Pancreatic Amylase
3. NIST, SRM 909b for Creatinine and Lithium.

Description of modifications:

The modified CLIN CHEM CAL assay is substantially equivalent to the original CLIN CHEM CAL assay K051452. The modifications consisted of certification in the following new analytes

1. **Lithium**
2. **Creatinine**
3. **Cholinesterase Dibucaine-Inhibited**
4. **Alpha Beta Hydroxybutyrate Dehydrogenase.**

All the above listed analytes are already contained in the original CLIN CHEM CAL. Thus no modifications of the chemical's compositions nor the production procedures have been made for the Clin Chem Cal (K051452).

These modifications did not significantly change the safety and effectiveness of the device as demonstrated in the Performance Characteristics Summary.

Intended Use:

Multiparameter calibrator [CCC-S] for quantitative clinical chemistry determinations. Sentinel Clin Chem Cal must be used for the calibration of clinical chemistry tests.

Description of the Calibrator Material:

Sentinel Clin Chem Cal contains the analytes in a lyophilized human serum matrix. The analytes consist of:

1. Pancreatic Amylase
2. Cholinesterase
3. Cholinesterase Dibucaine-inhibited
4. Lithium
5. Creatinine
6. Alpha-Beta Hydroxybutyrate Dehydrogenase.

Assigned Values and Value Assignment Process:

Target value assignment procedure is described in internal official protocol and under defined conditions.

Thirty (30) randomly selected vials of calibrator are reconstituted by weight (acceptability 2.970-3.030 g) following the Instruction for Use. (See page 28 for draft Instructions for Use)

The reconstituted vials are pooled in two (2) pools (15 vials in pool A and 15 different vials in pool B). The pools are aliquoted in small volumes (800 - 1200 µL) and the aliquots are labelled and stored at -20 °C.

On Abbott ARCHITECT® c8000 System (K980367), the following assays:

1. Pancreatic Amylase
2. Cholinesterase
3. Cholinesterase Dibucaine-inhibited
4. Lithium
5. Creatinine
6. Alpha-Beta Hydroxybutyrate Dehydrogenase.

are calibrated against an Internal Master Lot, stored at -20 °C and freshly thawed. During each testing run the following samples are tested:

1. Two levels (normal and abnormal) of control materials in triplicate to ensure the effectiveness of the measurements
2. Aliquot of Internal Master lot in triplicate
3. Aliquots of pool A and Pool B in triplicate.

Four (4) analytical runs on at least two different days are performed.

Single run is accepted if % recovery of each control material is within 85% - 115% and if % recovery of Internal Master lot is within 95%-105%.

The mean and Standard Deviation and %CV of the all measurements of pool A and Pool B are calculated. Data are inspected for outlier detection (single data – Mean > 3SD) and for imprecision of the measurements according to predefined criteria.

In case of absence of outliers and of imprecision $\leq 4.5\%$, the obtained mean is the Target value.

Directions for Use:

Refer to Draft Calibrator Labelling on page (See Appendix page 25 & 26 for draft Instructions for Use)

Performance Characteristics:

Please refer to Section III .

Conclusion:

The modified CLIN CHEM CAL assay is substantially equivalent to the Predicate Device and to the previous Cleared CLIN CHEM CAL as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Sentinel CH.
c/o Fabio Rota
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Milan Italy 20152

MAY 23 2007

Re: k070971
Trade/Device Name: Sentinel Clinical Chemistry Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: March 30, 2007
Received: April 06, 2007

Dear Fabio Rota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

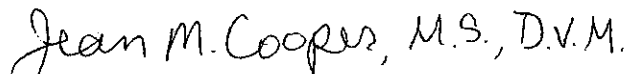
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

K070971

Device Name: CLIN CHEM CAL

Indications For Use

Clinical Chemistry – The Sentinel Clin Chem Cal is a device intended for medical purposes for use in Pancreatic amylase, Cholinesterase, Creatinine, Lithium, Alpha-Hydroxybutyrate Dehydrogenase and “Cholinesterase Dibucaine-Inhibited” assays to establish points of reference that are used in the determination of values in the measurement of Pancreatic amylase, Cholinesterase, Creatinine, Lithium, Alpha-Hydroxybutyrate Dehydrogenase and “Cholinesterase Dibucaine-Inhibited” in human specimens.

Prescription Use X_____

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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